K011439

SECTION 2: SUMMARY AND CERTIFICATION

A. 510(k) SUMMARY

NOV 0 2 2001

SUBSTANTIAL EQUIVALENCE:
Identification of predicate device, model and manufacturer:

Predicate device:	CardioDynamics BioZ.com Hemodynamic Monitor
Model:	BZ-4110
Manufacturer:	CardioDynamics International Corp.
Predicate Device 510(k):	K001100
Reason for Submission:	Design Modifications

The Bioz.com Hemodynamic Monitor is substantially equivalent to its predicate device, itself, the BioZ.com Hemodynamic Monitor currently marketed by CardioDynamics International Corp. The justification for this substantial equivalence determination is presented below.

The Bioz.com Hemodynamic Monitor is substantially equivalent to the BioZ.com Hemodynamic Monitor in terms of design, intended use and principal of operation. The Bioz.com Hemodynamic Monitor has undergone a redesign of internal components that do not affect its performance, safety, or efficacy. The redesign of internal components is intended to improve the manufacturability of the Monitor.

The intended use of the BioZ.com is to noninvasively measure a patient's hemodynamic parameters using Impedance Cardiography (ICG). Monitoring is accomplished by attaching 8 electrodes to the patient (two on each side of the neck and thorax) and injecting a minimal current through the outer electrodes and reading the returning voltage waveform from the inner electrodes.

The BioZ.com Hemodynamic Monitor utilizes CardioDynamics' proprietary DSP electronic circuitry and software incorporating formulas and algorithms to calculate the various hemodynamic parameters. The user inputs patient parameters into the Bioz.com, including patient gender, body frame size, height, weight, age and blood pressure. The Monitor then utilizes these parameters and measures the ICG signals to determine the hemodynamic properties of that particular patient.

The design modifications to the original system are found at the component and subsystem level. Design modifications were made to improve the manufacturability of the device. Manufacturability improvements were accomplished by consolidating electronic circuit boards, designing in more readily available subsystems and identifying alternate sources of equivalent subsystems to improve our ability to procure needed components. Software changes allow the new CPU to communicate with new or alternate subsystems. Users will not experience any difference between the predicate and new design as a result of the software or hardware changes. The differences between the predicate and new device designs are shown in Table 1.

Component/Subsystem	Original Design	Design Modification
Central Processing CPU	Intel 386 Processor and support circuits built onto the mother board.	Advance Digital Logic Model MSM386SV4 PC 104 CPU. The purchased 386 compatible PC 104 is mounted onto the new mother board.
Patient Interface Circuitry	Contained on a separate electrically isolated patient board which is then connected to the mother board.	Incorporated into an electrically isolated area of the new mother board.
Mother Board	16 layer printed circuit board. Contains an Intel 386 processor and support circuits. Connected to a separate electrically isolated patient board.	6 layer printed circuit board. Connects to a PC 104 processor and contains electrically isolated patient circuitry.
Power Supply	Condor Model GPM55-12 medical grade 12 volt power supply.	EOS Model MVLT60-1201 medical grade 12 volt power supply.
Nickel Metal Hydride Rechargeable Battery	Moltech Model NJ 1020	Harding Model OAXCRDY10
Noninvasive Blood Pressure Module	CAS Model 01-03-0074	Alternate source: SunTech Model "Advantage"
Electroluminescent Display	Planar Model EL320.240.36	Luxell Model LAEL 320.240_6F
I/O Board	Isolated Ground	Non-isolated Ground
Software	Version 2.27	Version 3.0 allows the new PC 104 CPU to communicate with the SunTech blood pressure module and Luxell electroluminescent display. Users will not see any difference in operation of the device.

Table 1 – Summary of BioZ.com Design Modifications

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 2 2001

Mr. Brian J. Park
CardioDynamics International Corporation
6175 Nancy Ridge Drive, Suite 300
Dan Diego, CA 92121

Re: K011439
Trade Name: BioZ.com® HemoDynamic Monitor
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB
Dated: August 3, 2001
Received: August 6, 2001

Dear Mr. Park:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 2 2001

510(k) Number (if known): K011439

Device Name: BioZ.com® Hemodynamic Monitor

Indications for Use:

The BioZ.com® Hemodynamic Monitor is intended to monitor and display a patient's hemodynamic parameters. These parameters include:

ECG	Pre-Ejection Period	Systolic Time Ratio
Heart Rate	Left Ventricular Ejection Time	Thoracic Fluid Content
Cardiac Output	System Vascular Resistance	End Diastolic Volume
Cardiac Index	System Vascular Resistance Index	End Diastolic Index
Stroke Volume	Left Cardiac Work	Index of Contractility
Acceleration Index	Left Cardiac Work Index	Respiration Rate

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of DCRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR Over-The-Counter Use** _____
(Per 21 CFR 801-109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011439